

Notice of Allowability

Application No.

10/056,298

Examiner

Shaojia A Jiang

Applicant(s)

CHOVET ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 5, 2003 and January 20, 2004.
2. ☒ The allowed claim(s) is/are 2-4, 6-9, and 15-18 (now renumbered to 1-11).
3. ☒ The drawings filed on 25 January 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SHAOJIA ANNA JIANG
PATENT EXAMINER
4/8/04

DETAILED ACTION

Applicant's amendment and remarks submitted November 5, 2003 is acknowledged wherein no claims are amended or cancelled, and claims 15-20 are newly added.

Applicant's supplemental amendment and remarks submitted January 20, 2004, wherein claims 1, 5, and 10-14 are cancelled, and claims 2-4 and 6-9 have been amended.

The terminal disclaimer filed on November 5, 2003, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. 6,596,900 (Application No. 10/124,210) has been reviewed and is accepted. The terminal disclaimer has been recorded.

As pointed out in the previous Office Action May 7, 2003, acknowledgment is made of applicant's claim for foreign priority to EPO 01400214.1 under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant Application filed on January 25, 2002.

The reasons for allowance will be discussed below.

Examiner's Amendment

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. David R. Kurlandsky on April 8, 2004.

In the claims:

Cancel pending claims 19-20.

Reasons For Allowance

Currently, claims 2-4, 6-9, and 15-18 are pending in this application.

Claims 2-4, 6-9, and 15-18 have been examined on the merits herein.

The claimed method for treating gastrointestinal disorders and method of irritable bowel syndrom compdsing administering to a patient in need of treatment an effective amotmt of a compound of formula I-IV, is not seen to be taught or fairly suggested by the prior art, as discussed below.

Applicant's amendment submitted January 20, 2004 which deletes the recitation "preventing" in the independent claim 2, has been considered and is sufficient to remove the rejection of claims 2-4 and 6-9 made under 35 U.S.C. 112, first paragraph, for lack of scope of enablement for a method for preventing GI disorders, of record in the previous Office Action May 7, 2003, as suggested by the examiner in the telephonic interview (see the interview summary).

Moreover, the instant specification is seen to provide the enabling information to practice invention herein for a method of treating GI disorders by administering the instant compound without undue experimentation. For example, the specification teaches that the particular compound (Ia) within the scope of what is claimed (which is the instant compound in claims 6 and 18, see the structure at page 3 lines 14-18 of the specification) not only possesses therapeutic effects of gabapentin but also 500 fold more potent than gabapentin for the treatment of visceral disorders (see the last paragraph of page 26). The specification also shows the factual evidence of the testing results as working

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examples that the particular compound (Ia) is useful in treating chronic visceral allodynia in rats by comparing the testing results with gabapentin (see Example 10 at page 51-53), and this compound also has antihyperalgesic activity on bacterial lipo-polysaccharide induced rectal hypersensitivity but also displays a more potent antihyperalgesic activity than gabapentin does (see Example 11 at page 54-56).

Further, the particular compound (Ia) is seen to be a representative of the instant compounds in claim 2, since all instant compounds in claim 2 are deemed to be structurally close related or structurally similar compounds having γ -amino carboxylic acid (see Formula in claim 2 herein). Thus, one of ordinary skill in the art would have reasonably expected that the particular compound (Ia) and the rest of instant compounds in the claims, would have same or substantially similar beneficial therapeutic effects and usefulness in methods for treating GI disorders in a patient, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, as noted in MPEP 2144.

Thus, the specification is deemed to provide sufficient support and enablement for the claimed invention herein, as discussed above.

The terminal disclaimer filed on November 5, 2003, with respect to the rejection of claims 2-4 and 6-9 made under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the method claims 7 and 8 of 6,596,900 (Application No. 10/124,210) in view of Bryans et al.

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(WO 99/21824) of record in the previous Office Action May 7, 2003, has been considered and found persuasive to overcome this obviousness-type double patenting rejection.

Claims 19-20 have been cancelled in the examiner's amendment set forth above as being drawn to a nonelected invention.

Accordingly, Applicant's amendment submitted January 20, 2004, and the terminal disclaimer filed on November 5, 2003 in the accompanying examiner's amendment are sufficient to remove all rejections made in the prior Office Action as discussed above and place the application in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

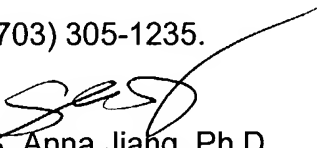
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is 571.272.0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on 571.272.0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is

(703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 8, 2004

SHAOJIA ANNA JIANG
PATENT EXAMINER